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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,125	09/09/2003	Tomas Hagstrom	Strom.7293	9693

7590 09/12/2006

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/658,125	HAGSTROM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Barbara P. Badio, Ph.D.	1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 29-72 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 and 33-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Election/Restrictions***

2. Claims 1, 5 and 29-42 are pending in the present application. Claims 29-31 and 33-42 stand withdrawn as being drawn to a nonelected invention. Claim 32 will be examined to the extent it reads on compounds of formulae (I) and (II). Thus, claims 1, 5 and 32 will be examined according to MPEP § 803.02.

***Claim Rejections - 35 USC § 112***

3. The rejection of claim 1 under 35 USC 112, second paragraph is maintained.

The instant claim as amended reads "a protecting group, in the form of such as CH<sub>3</sub>...". As indicated in the previous Office Action, the phrase "such as" makes the claim indefinite because it is unclear whether the limitations following said phrase are part of the claimed invention. It is suggested that the above-mentioned phrase be rewritten as "a protecting group, in the form of CH<sub>3</sub>...".

For this reason, the rejection of claim 1 under 35 USC 112, second paragraph is maintained.

***Claim Rejections - 35 USC § 102***

**4. The rejection of claims 1 and 5 under 35 USC 102(e) over Ahlem et al. (US 6,667,299) is maintained and claim 32 is rejected under 35 USC 102(e) over Ahlem et al. (US 6,667,299).**

Applicant argues the reference lacks physical data/evidence or other data indicating the existence of the prior art compounds without a 16-substituent. Therefore, applicant argues the claimed compounds are not anticipated by the reference. Applicant's argument was considered but not persuasive for the following reasons.

The reference is a US patent and, thus, is enabled for that which is disclosed in therein. In addition, a reference is evaluated based on what it teaches not what is exemplified, for example, the presence of physical data of the prior art compound(s). Therefore, applicant's argument that the reference does not provide any physical evidence or other data of the existence of the claimed compound is noted but not relevant. As stated in the previous Office Action, the reference teaches a genus of steroidal compounds including 5-androstene-3 $\beta$ ,7 $\beta$ ,17 $\alpha$ -triol (see RN 459812-86-3; Table B, compound #1.2.5.2; col. 53, Group 2 and col. 68, lines 11-15). The compound taught by the reference is encompassed by the instant claims (see for example, claim 5, compound #1).

For this reason and those given in the previous Office Action, the rejection of claims 1 and 5 under 35 USC 102(e) over Ahlem et al. (US 6,667,299) is maintained and claim 32 is rejected under 35 USC 102(e) over Ahlem et al. (US 6,667,299).

***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

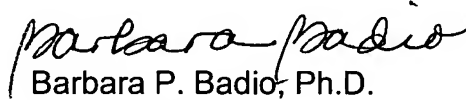
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
September 6, 2006